REMARKS

Claims 1-4, 14-19, 21, 22, 25-29 and 33-48 are now in the application. Claims 1-4, 14-19, 21, 22, 25-29, 33, 34, 35 and 40-48 are directed to the elected species. Claims 36-39 are directed to non-elected species.

Claims 25 and 26 have been amended by reciting "at least one ion exchange resin" in place of "taste masking agent" for purposes of clarification and consistency with claim 1 and not to restrict their previous scope. Claim 27 has been amended by deleting the phrase "said taste masking agent is an ion exchange resin, and" for purposes of clarification and consistency with claim 1 and not to restrict its previous scope.

Newly presented claim 40 corresponds to prior claim 4 except that it depends from claim 2 instead of claim 1. Newly presented claim 41 finds basis in the specification, for example, at page 23, line 18. Newly presented claims 42-44 finds basis in the specification, for example, at page 15, lines 14-16. Newly presented independent claim 45 recites as active agent, the Markush group from claim 4 and selected water soluble polymers from claim 2. New claims 46, 47 and 48 correspond to claims 35, 36 and 39, respectively except that they depend from claim 45 instead of claim 1.

The amendments to the claims and newly presented claims 40-48 do not introduce any new matter.

The rejection of claims 25-27 under 35 USC 112, second paragraph has been overcome by the above mentioned clarifying amendments to these claims.

The rejection of claims 1-4, 14-19, 21, 22, 28, 29 and 33-39 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-20 of US Patent 6,596,298 to Leung will be overcome by the filing of a terminal disclaimer. Such will be filed upon overcoming the remaining rejections in this application. The filing of a terminal disclaimer is not to be construed as an admission, estoppel or acquiescence. See *Quad Environmental Technology v. Union Sanitary District*, 20 USPQ2d 1392 (Fed. Cir.1991) and *Ortho Pharmaceuticals Corp. v. Smith*, 22 USPQ2d 1119 (Fed.Cir.992).

Claims 1-4, 7, 14-19, 21, 22, 25-29 and 33-39 were rejected under 35 USC 103(a) as being obvious over U.S. Patent 5,980,882 to Eichman in view of US Patent 5,411,945 to Ozaki, et al.(herein also referred to as "Ozaki") or US Patent to Schiraldi et al.(herein also referred to as "Schiraldi"). Eichman in view of Ozaki, et al. or Schiraldi et al. fail to render obvious the above claims.

The above claims relate to an orally consumable solid film that comprises at least one water soluble polymer, an adsorption complex that comprises at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent or method of making the orally consumable solid film. The film is adapted to adhere to and dissolve in the mouth of a consumer.

Eichman fails to suggest the present invention since, among other things, Eichman does not even remotely suggest that the complexes discussed therein could or should be used in orally-consumable solid films containing at least one water soluble resin. Eichman states that the composition can be in the form of a tablet, a capsule, a powder, a lotion, a cream, a suppository, a syrup, a suspension, a nasal spray, an inhaler or an eye drop(see column 5, lines 31-37 and column 13, lines 30-37). Although, Eichman mentions numerous possible forms in which the compositions could possibly be used, Eichman is completely silent concerning films and films are not even remotely suggested in the disclosure by Eichman. The statement in the office action that the drug-resin complex coated with a film as disclosed by Eichman is "an orally consumable film" is in error. Eichman refers to using ethyl cellulose, a **water insoluble** material, as the coating. Accordingly, the coated particles of Eichman are not films that dissolve in the mouth. Furthermore, Eichman refers to coating finely divided powder or granules and not to forming films. In addition, the coated finely divided powder or granules of Eichman are not films adapted to adhere to and dissolve in the mouth of a consumer as recited in the present claims.

The conclusion in the office action that the product of Eichman would be expected to be less gritty because the product has improved dissolution characteristics is also in error. No relationship exists between dissolution properties and grittiness. Something can be readily dissolvable and feel very gritty, while a non soluble material might be quite soft and smooth. Also, the dissolution characteristics desired by

Eichman relate to employing a diffusion barrier which would prolong the dissolution of the drug-resin complex. It is not at all apparent why this would have any relevance to reduced grittiness.

Ozaki was relied upon for a disclosure of the film-forming ability of pullulan. However, Ozaki fails to suggest that films of pullulan could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin to obtain an orally-consumable solid film. In fact, Ozaki even fails to suggest a film containing a pharmaceutically active agent. Instead, Ozaki suggests using films for wrapping an "unswallowable powdery medicine" that is similar to a medicinal wafer (see column 8, lines 11-26). This configuration is quite different from an orally consumable film that is adapted to adhere to and dissolve in the mouth of a consumer as recited in the present claims. Moreover, it was surprising that the ion-exchange resin could even be employed with and not be incompatible with the water soluble polymer. This was surprising in view of the differences in solubility characteristics between the water soluble polymer and the ion exchange resin, which are disclosed as and known as not being water soluble.

Schiraldi does not overcome the above discussed deficiencies of Eichman and Ozaki with respect to rendering obvious the present claims. Schiraldi was merely relied upon for a disclosure of a pharmaceutical film containing a pharmaceutical agent and hydroxypropylcellulose adhering to a wet mucous surface. However, Schiraldi fails to suggest that films therein could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin to obtain an orally-consumable solid film. The structures of Schiraldi are intended to adhere to and remain in place over an extended period of time to provide controlled release of a pharmaceutical agent at the location wherein the film is placed. This is in contrast to the fast dissolving films of the present invention.

The cited art lacks the motivation for forming an orally consumable solid film of a water soluble resin and complex of a pharmaceutically active agent and an ion exchange resin. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103.

The mere fact that cited art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the cited art suggest the desirability of the modification. No such suggestion appears in the cited art in this matter. The Examiner's attention in kindly directed to *In re Lee* 61 USPQ2d 1430 (Fed. Cir.2002), *In re Dembiczak et al.* 50 USPQ2d. 1614 (Fed. Cir.1999), *In re Gordon*, 221 USPQ 1125 (Fed. Cir.1984), *In re Laskowski*, 10 USPQ2d. 1397 (Fed. Cir. 1989) and *In re Fritch*, 23, USPQ2d. 1780 (Fed. Cir.1992).

In *Dembiczak et al.*, supra, the Court at 1617 stated: "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc., v. M3 Sys., Inc., 157 F.3d. 1340, 1352, 48 USPQ2d. 1225, 1232 (Fed. Cir. 1998) (describing 'teaching or suggestion motivation [to combine]' as in 'essential evidentiary component of an obviousness holding'), In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d. 1453, 1459 (Fed. Cir. 1998) ('the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them');...".

The combination and balance of different properties that would be desired from the type of product to which this invention is directed are quite difficult to achieve. For instance, along with masking the taste of the active agent, the limitations on the size or volume of the film place demands on being able to achieve sufficient dosage of the active agent. This is to be accomplished without the need for unduly increasing the volume or dimensions of the film so as not to lose the advantage of its convenience. As discussed above, it was surprising that the ion-exchange resin could even be employed with and not be incompatible with the water soluble polymer. This was surprising in view of the differences in solubility characteristics between the water soluble polymer and the ion exchange resin, which are disclosed as and known as not being water soluble.

Furthermore, it was not predictable that the presence of the ion exchange resin would be beneficial without adversely affecting the properties of the film such as damaging its integrity, or causing brittleness, grittiness or another undesirable feel, or

dehydrating the film to an undesired extent. In fact, attempts at coating the active agent and using the coated component in a film of a water soluble polymer, e.g. pullulan, resulted in a gritty and bitter product.

Along these lines, please see the comparative films in examples 1, 2 and 3 (Tables 1, 2 and 3) on pages 22-27 of the specification. On the other hand, films employing complexes of pharmaceutically active agents and ion exchange resins in accordance with the above claims exhibit desired appearance and taste characteristics. Please see examples 4-7 (Tables 4-7) on pages 27-32 of the specification.

The statement in the office action that the comparative examples are limited to the use of dextromethorphan as an active agent and the use of pullulan as a film forming agent and it cannot be predicted if additional agents encompassed by the instant claims will result in a film having desired property is misplaced. Nothing in the record suggests that the use of other materials encompassed by the instant claims would result in vastly different characteristics. Also, the claims are at least implicitly limited by common sense, if nothing else, to those combinations that form orally consumable films that are adapted to adhere to and dissolve in the mouth of a consumer. Furthermore, the comparative films shown are deemed to be a comparison to the closest prior art and to require more places an unjustified and undue burden and expense on the applicant. This is especially so in the present situation since a case of *prima facie* obviousness has not even been established. In fact the above statement in the office action runs counter to the case law such as *In re Goffe*, 191 USPQ 429, 431 (CCPA, 1976). While discussing a different rejection, but nonetheless relevant to the present situation, the Court made the following precautionary statement:

> " For all practical purposes the Board would limit appellants to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute . However to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet guidelines specified for 'preferred materials' in a process such as

the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts".

Also, the cited art lacks the necessary direction or incentive to those of ordinary skill in the art to render the rejection under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention, as discussed above, needed to sustain a rejection under 35 USC 103. See *Diversitech Corp. v. Century Steps, Inc.* 7 USPQ2d 1315 (Fed. Cir.1988), *In re Mercier*, 185 USPQ 774 (CCPA 1975) and *In re Naylor*, 152 USPQ 106 (CCPA 1966).

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d. 1923 (Fed.Cir. 1990), *In re Antonie*, 195, USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the cited art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

The rejection of the claims is in the nature of "ought to be tried" which is an impermissible standard under 35 U.S.C. 103. See *Jones v. Hardy*, 220 USPQ 1021 (Fed.Cir., 1984).

Accordingly, the cited art fails to render obvious the above claims.

In view of the above, consideration and allowance are, therefore, respectfully solicited. In the event that the Examiner believes that another interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication including any extension fees to Deposit Account No. 22-0185.

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Respectfully submitted,

By _____

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